Department of Veterans Affairs **VHA DIRECTIVE 1058**
Veterans Health Administration
Washington, DC 20420 **October 28, 2004**

RESPONSIBILITIES OF THE OFFICE OF RESEARCH OVERSIGHT

1. REASON FOR ISSUE. This Veterans Health Administration (VHA) Directive defines the policy and responsibilities of the Office of Research Oversight (ORO) (10R) within VHA.

2. SUMMARY OF CONTENTS AND/OR MAJOR CHANGES. ORO serves as the primary VHA office in advising the Under Secretary for Health on all matters of compliance and assurance for human subjects' protections, animal welfare, research safety and security, research impropriety, and research misconduct. ORO promotes and enhances the responsible conduct of research in these areas in conformance with laws, regulations, and policies. In December 2003 the President signed Public Law 108-170 that created by statute the Office of Research Oversight. The responsibilities described in this Directive indicate those of ORO by statute and given administratively by the Under Secretary for Health.

3. RELATED ISSUES. VHA Handbook 1058.1.

4. RESPONSIBLE OFFICIALS. The Chief Officer, ORO (10R), is responsible for the contents of this Directive. Questions may be referred to (202) 565-7191 or (202) 565-4835.

5. RESCISSIONS. VHA Directive 1058 dated May 23, 2001, is rescinded.

6. RECERTIFICATION. This VHA Directive is scheduled for recertification on/before the last working day of October 2009.

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RESPONSIBILITIES OF THE OFFICE OF RESEARCH OVERSIGHT

1. PURPOSE: This Veterans Health Administration (VHA) Directive defines the policy and responsibilities of the Office of Research Oversight (ORO) (10R) within VHA.

2. BACKGROUND:

a. Public Law 108-170, enacted December 2003, established ORO by statute. ORO is the primary office in VHA for overseeing the responsible conduct of research and investigations of allegations of research misconduct. ***NOTE:*** *ORO refers to the laws, regulations, and policies such as those cited in paragraph 6, References, to facilitate research compliance in VHA.*

b. ORO serves as the chief VHA office for liaison regarding assurance and compliance with such offices as: the Office for Human Research Protections (OHRP), the Office of Laboratory Animal Welfare (OLAW), the Food and Drug Administration (FDA), and the Office of Research Integrity (ORI) in the Department of Health and Human Services (DHHS); other Federal departments, and agencies with like responsibilities, including signatories to the "Common Rule" and various other external groups such as medical and dental school affiliates and professional organizations.

c. ORO Central Office provides oversight to its Regional Offices, the main operational components in ORO that develop the necessary working-level arrangements with VHA facilities (VHA medical centers, VHA health care systems, and VHA medical and regional office centers) and Veterans Integrated Service Networks (VISNs). The Regional Offices execute ORO's program for human subjects' protections, animal welfare, research safety, and research security through routine, or for cause reviews. ORO Central Office manages research misconduct oversight.

3. POLICY: It is VHA policy that ORO serves as the primary VHA office in advising the Under Secretary for Health on matters of compliance and assurance in human subjects' protections, animal welfare, research safety and security, research impropriety, and research misconduct.

4. RESPONSIBILITIES: ORO promotes and enhances the responsible conduct of research in conformance with Federal and/or VA laws, regulations, and policies; it is responsible for:

a. Reviewing allegations and/or findings of non-compliance with laws, regulations, and policies.

b. Performing periodic prospective reviews at each VHA facility engaged in research to assure compliance with such laws, regulations, and policies.

c. Overseeing inquiries and investigations of allegations of research misconduct, and conducting investigations, as appropriate.

d. Overseeing the reporting of human subjects' protections, animal welfare, research safety and security, research improprieties, and research misconduct compliance issues.

e. Managing, in collaboration with OHRP, Federal Wide Assurances, or other assurances with each VHA facility conducting human subjects' research, and managing other assurances, as appropriate.

f. Advising on Memoranda of Understanding regarding human research protections programs.

g. Collaborating with other Federal and VHA offices on the interpretation of policies and procedures regarding human subjects' protections, animal welfare, research safety and security, research improprieties, and research misconduct.

h. Monitoring external accreditation activities conducted for VHA research programs. ***NOTE:*** *This is accomplished, in part, by reviewing reports from external accreditation organizations.*

i. Developing specific areas of emphasis and expertise in research assurance and compliance activities.

j. Providing technical assistance and information to VHA research facilities and other audiences, as appropriate, to enhance and promote research compliance.

k. Submitting by March 15 of each year a report to the Committees on Veterans' Affairs of the Senate and House of Representatives on the activities of ORO during the preceding calendar year. The report includes:

(1) A summary of reviews of individual medical research programs completed by ORO,

(2) Directives and other communications issued by ORO to the field,

(3) Results of any investigations by ORO, and

(4) Other pertinent information about ORO.

l. Reporting to the Under Secretary for Health, the Secretary, and the Committees on Veteran's Affairs of the Senate and House of Representatives any suspected lapse, from whatever cause or causes, in protecting the safety of human subjects and others, including employees, in VA medical research programs.

5. DEFINITIONS

a. **External Accreditation.** VHA contracts with external accrediting organizations to carry out reviews of VHA facilities conducting research involving human subjects or animals to ensure that they are complying with appropriate laws**,** regulations, policies, and procedures. The National Committee for Quality Assurance (NCQA) is the accreditation organization for the human research protection programs. The Association for Assessment and Accreditation of

Laboratory Animal Care International (AAALAC) is the accreditation organization for animal care and use programs.

b. **Adverse Event (AE) in Research.** An AE in research is any untoward occurrence (physical, psychological, social, or economic) in a human subject participating in research. An AE in research can be any unfavorable or unintended event, including abnormal laboratory finding, symptom or disease, or death associated with the research or the use of a medical investigational test article.

NOTE: *An AE in research may occur even in the absence of any error or protocol deviation, and does not necessarily have to be caused by any identifiable aspect of the research.*

c. **Assurance of Compliance (Care and Use of Laboratory Animals).** An assurance of compliance is a legally-binding written document between OLAW and the VHA Institutional Official that the VHA facility will carry out its regulatory and policy responsibilities for animal welfare. All VA animal research must be covered by a Public Health Service Assurance.

d. **Assurance of Compliance (Human Subjects).** An assurance of compliance is a legally-binding written document that commits a VHA facility to comply with the Common Rule and other applicable Federal and VA standards for the protection of human subjects. It is an agreement signed by the Institutional Official (VHA facility Director), OHRP, and through a VA Addendum, the Network Director, and ORO CO. An approved assurance is a prerequisite to conducting human subjects research in VA.

e. **ORO Activities.** ORO uses both prospective and retrospective reviews to oversee VHA facilities carrying out research. These reviews may be accomplished by on-site visits, or through other forms of communications.

f. **ORO Regional Offices.** ORO field offices are headed by an ORO Regional Office Director and include a staff that fulfills the full scope of compliance and assurance responsibilities. Each Regional Office interacts with several VISN offices, VHA facilities, and ORO CO to carry out assurance and compliance activities.

g. **Research.** For purposes of this Directive, research is medical research described in Title 38 United States Code (U.S.C.) 7303 (a)(2). This includes biomedical research, mental illness research, prosthetic and other rehabilitative research, and health care services research.

h. **Research Impropriety.** For purposes of this Directive, the term research impropriety refers to non-compliance with laws, regulations, and policies regarding protection of human subjects, animal welfare, safety, security, and research misconduct. It does not encompass improper procedures or conduct in areas outside of the mandate of ORO, for example, waste, fraud, abuse, or fiscal mismanagement.

i. **Research Misconduct.** Research misconduct is the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

j. **Research Safety and Security Program.** The Research Safety and Security Program is concerned with laboratory practices, techniques, equipment, and facilities appropriate for the safe and secure operations performed and the hazards posed in VA research.

6. REFERENCES

a. Public Law 108-170, Section 401, Office of Research Oversight in Veterans Health Administration, codified at 38 U.S.C. 7307.

b. Title 7 U.S.C. Sections 2131-2156, the Federal Animal Welfare Act.

c. Title 38 U.S.C. 7303.

d. Title 7 Code of Federal Regulations (CFR) 331.

e. Title 9 CFR Parts 1, 2, 3, and 121.

f. Title 10 CFR Chapter 1, Parts 19, 20, and 35.

g. Title 21 CFR Parts 50, 54, 56, 312, 314, 600, 812, and 814.

h. Title 29 CFR Parts 1910 and 1960.

i. Title 38 CFR Parts 16, 17.33, and 17.85.

j. Title 40 CFR Chapter 1, Parts 260, 261, and 262.

k. Title 42 CFR 73.

l. Title 45 CFR 46.

m. Federal Register 76260 (December 6, 2000).

n. The Guide for the Care and Use of Laboratory Animals. The Institute of Laboratory Animals Resources Commission on Life Sciences, National Research Council, National Academy Press, Washington, DC, 1996.

o. Public Health Service Policy on Humane Care and Use of Laboratory Animals, 1986.

p. Centers for Disease Control and Prevention (CDC) National Institutes for Health (NIH) Biosafety in Microbiological and Biomedical Laboratories, 4th Edition, May 1999.

q. NIH Guidelines for Research Involving Recombinant DNA Molecules, April 2002.